

The opinion in support of the decision being entered today was *not* written for publication and is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

---

*Ex parte* RICHARD WISNIEWSKI and  
LEONIDAS C. LEONARD

---

Appeal 2007-1673  
Application 10/056,237  
Technology Center 3700

---

Decided: April 30, 2007

---

Before EDWARD C. KIMLIN, BRADLEY R. GARRIS, and CHUNG K. PAK, *Administrative Patent Judges*.

KIMLIN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal from the final rejection of claims 1-8 and 27-42.

Claims 9-26 stand withdrawn from consideration. Claim 1 is illustrative:

1. A method of preserving a biopharmaceutical product in a vessel having an interior cavity defined by at least an interior wall of said vessel; actively cooling said interior wall using a fluid;

actively cooling a heat exchange structure within said cavity by flowing a fluid through a dual flow conduit having one or more heat transfer members thermally coupled thereto;

freezing said medium within said vessel to preserve said biopharmaceutical product.

The Examiner relies upon the following references as evidence of obviousness:

West US 2,114,642 Apr. 19, 1938

Kalhor, "Studies on Heat Transfer From a Vertical Cylinder, With or Without Fins, Embedded in a Solid Phase Change Medium," *Transactions of the ASME, Journal of Heat Transfer*, Vol. 107, 44-51 (Feb. 1985).

Wisniewski, "Large-Scale Freezing and Thawing of Biopharmaceutical Drug Product," *Proceedings of the International Congress, Advanced Technologies For Manufacturing of Aseptic & Terminally Sterilized Pharmaceuticals & Biopharmaceuticals*, 133-139 (Feb. 1992).

Appellants' claimed invention is directed to a method of preserving a biopharmaceutical product by freezing a medium comprising the product in a vessel whose interior wall is actively cooled. Also, a heat exchange structure within the cavity of the vessel is actively cooled by flowing a fluid through a dual flow conduit having one or more heat transfer members thermally coupled thereto.

Appealed claims 1-8 and 27-42 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wisniewski in view of Kalhori and West.

The Examiner has withdrawn the rejection under 35 U.S.C. § 112, second paragraph.

Appellants do not contest the Examiner's determination that claims 1-8 and 27-34 stand or fall together, as do claims 35-42 (see page 3 of Answer).

We have thoroughly reviewed each of Appellants' argument for patentability. However, we are in complete agreement with the Examiner that the claimed subject matter would have been obvious to one of ordinary skill in the art within the meaning of § 103 in view of the applied prior art. Accordingly, we will sustain the Examiner's rejections for essentially those reasons expressed in the Answer.

There is no dispute that Wisniewski, like Appellants, discloses a method of preserving and freezing a biopharmaceutical product inside a vessel by actively cooling both the interior wall of the vessel and a heat exchange structure located within the vessel. As acknowledged by the Examiner, Wisniewski does not disclose actively cooling the heat exchange structure within the vessel by flowing a fluid through a dual flow conduit. However, Appellants do not dispute the Examiner's factual determination that both Kalhori and West evidence that it was known in the art to employ heat exchange structures comprising a dual flow conduit for freezing medium within a vessel. Accordingly, based on the collective teachings of the applied references, we concur with the Examiner that it would have been *prima facie* obvious for one of ordinary skill in the art to employ the known dual flow conduit in the system of Wisniewski for freezing and preserving a biopharmaceutical product. The Examiner has supplied the requisite motivation at page 24 of the Final Rejection, namely, (1) for improving heat

transfer, (2) to facilitate ease of construction, and (3) to facilitate easy removal of the frozen mass.

Appellants have presented no rationale why one of ordinary skill in the art would have been dissuaded from using the known dual flow heat exchange structure in the system of Wisniewski. Nor have Appellants proffered any evidence of unexpected results attached to the use of the known heat exchange structure. Indeed, it would appear that Appellants' Specification attaches no particular criticality to the use of a dual flow structure. In particular, Appellants' Specification states:

It should be appreciated that one skilled in the art could use other flow patterns, fin shapes, and fin configurations to induce the medium to heat or cool in any preferred direction, uniformly, and/or at a specified rate without departing from the present invention. Additionally, parameters of the heat exchange fluid such as flow rate and/or temperature can be used to affect the rate at which the medium is cooled.  
[See paragraph [0067]].

Appellants' principal contention is that there is no disclosure or suggestion in Kalhori that the external tank walls are actively cooled, but, rather, "the vessel is wrapped with an electrical band heater to warm the medium from the outside while the cylinder within is cooling it" (sentence bridging pages 12 and 13 of Principal Br.). However, it is fundamental that it is not required for a finding of obviousness that all the features of one reference be physically incorporated into another reference. The relevant inquiry is what the collective teachings of the prior art would have suggested to one of ordinary skill in the art. *In re Griver*, 354 F.2d 377, 381, 148 USPQ

197, 200 (CCPA 1966); *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). As recognized by Appellants, Kalhori is concerned with a study investigating the melting and cyclic melting and freezing around a vertical cylinder. Hence, the walls of the cylinder are heated. However, Kalhori, as well as West, evidence the obviousness of employing a dual flow conduit within a cylinder to freeze a liquid medium therein. Again, Appellants have advanced no reason why one of ordinary skill in the art would have considered the dual flow conduits of Kalhori and West inappropriate for the system of Wisniewski. While Appellants refer to declaration evidence in their Brief regarding special considerations for biopharmaceutical products, Appellants have offered no specific analysis and explanation of the particulars of the declarations, and it is not within the province of this Board to ferret out evidence in the record which supports Appellants' argument. Nor have Appellants set forth a convincing rationale why one of ordinary skill in the art would not have considered a dual flow conduit suitable for freezing biopharmaceutical products. Moreover, Appellants make no argument that the declaration evidence establishes unexpected results associated with methods of preserving biopharmaceutical products within the scope of the appealed claims.

As a final point, although the present application and appeal is related to co-pending appeals for applications U.S. Serial No. 08/895,396 (Appeal No. 2007-0867) and U.S. Serial No. 09/881,909 (Appeal No. 2006-3326), the claims of the present appeal do not recite

Appeal 2007-1673  
Application 10/056,237

the formation of a thermal bridge which forms the central issue in the co-pending appeals.

In conclusion, based on the foregoing and the reasons well stated by the Examiner, the Examiner's decision rejecting the appealed claims is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(iv)(effective Sept. 13, 2004).

AFFIRMED

cam

Brett M. Hutton, Esq.  
Heslin Rothenberg Farley & Mesiti, P.C.  
5 Columbia Circle  
Albany, NY 12203